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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,241	07/31/2003	J. Kenneth Burkus	4002-3366/PC361.16	1607

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INDIANAPOLIS, IN 46204-2709

EXAMINER
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SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/631,241	<b>Applicant(s)</b> BURKUS ET AL.	
	<b>Examiner</b> Richard R. Shaffer	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-23 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,23,27-33,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 17-22 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "first and second distractors" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 31 and 32 are rejected for depending upon an indefinite base claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 23, 27-33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US Patent 5,797,909) in view of Kohrs et al (US Patent 5,865,847).

Michelson discloses a method for preparing a spinal disc space for insertion of an implant to restore a desired lordotic angle comprising: inserting a guide sleeve (1310; **Figures 36-41**) from an anterior approach; the guide sleeve having a working channel (1352 and 1354 overlapping); distracting the disc space by inserting first and

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second reamer plugs (**1320, 1322**) having flat sides (**Column 38, Lines 7-15**) or being knurled, irregularly shaped cylinders, or partial cylinders (**Column 39, Lines 2-5**); the partial cylinders would include a recess along the entire length of the body, or would a flat side in reference to material missing from a complete cylinder; preparing a second disc space through one side of the working channel (**Column 38, Lines 15-21**); an optional reamer is secured within the working channel by being of the size of the internal dimension of the working channel; inserting a threaded implant (**Column 38, Lines 39-43**) into the second disc space; the implant is held in place (engaged) by the threads with the adjacent spinal end plates; removing the "first" plug in order to repeat the process (**Column 14, Lines 60-62, Column 16, Lines 58-60; Column 38, Lines 52-65**); a first embodiment (**Column 37, Lines 46-52**) has the guide sleeve inserted after the distractors have been inserted; an optional embodiment (**Column 16, Lines 9-25**), the guide sleeve and distractors can be inserted simultaneously with the use of an impaction cap.

Michelson fails to disclose an implant tapered to restore lordosis, but rather demonstrated that the distractors **could be** tapered to restore lordosis as well as hinting (**Column 38, Lines 1-5**) that other shapes are within the scope of his invention. Kohrs et al teaches a tapered spinal implant (**Figure 1**) and states (**Column 1, Lines 30-45**) that "it is desirable to provide an implant which maintains or achieves a desired lordosis between opposing vertebrae." It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the tapered implant teaching of Kohrs, et al to restore and maintain lordosis in the method of Michelson.

***Allowable Subject Matter***

Claims 17-22 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed on March 22nd 2006 in regard to the combination of Michelson and Kohrs et al for providing for a tapered implant have been fully considered but they are not persuasive. As emphasized in this current Office Action (was stated previously as well), Michelson merely said a tapered distraction tool was within the scope of the invention in order to correct for lordosis and kyphosis. Because Michelson saw the importance of correcting for the correct curvature of the spine, utilizing a tapered implant as taught by Kohrs et al would have been obvious to one having ordinary skill in the art at the time the invention was made to achieve the same result. It is further noted that Michelson does clearly disclose a working channel tool that does not distract the spinal disc space in any form. This is however irrelevant because what applicant is arguing in respect to the differences between an embodiment (one of many) of Michelson and applicant's invention were not claimed.

Applicant's remaining arguments with respect to claims 16, 23, 27-33, 35, and 36 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claims 17-22 and 34 have been fully considered and are persuasive. The rejection of claims 17-22 and 34 have been

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withdrawn and are not merely objected to for being dependent upon a rejected base claim

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Richard Shaffer*

Richard Shaffer  
June 10th, 2006

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER